

What is claimed is:

1. An inclusion complex of aripiprazole in a substituted beta-cyclodextrin.

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2. The inclusion complex as defined in Claim 1 wherein the β -cyclodextrin is sulfobutyl ether β -cyclodextrin (SBECD) or hydroxypropyl β -cyclodextrin (HPBCD).

10 3. The inclusion complex as defined in Claim 2 wherein the cyclodextrin is SBECD.

4. A pharmaceutical formulation comprising aripiprazole and a substituted β -cyclodextrin.

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5. The formulation as defined in Claim 4 in the form of an injectable formulation.

20 6. The formulation as defined in Claim 4 wherein the substituted β -cyclodextrin is sulfobutyl ether β -cyclodextrin (SBECD) or hydroxypropyl- β -cyclodextrin (HPBCD).

7. The formulation is defined in Claim 4 comprising an aqueous injectable formulation having a pH within the range from about 3.5 to about 5.

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8. The formulation as defined in Claim 7 including an acid buffer.

30 9. The formulation as defined in Claim 8 wherein the acid buffer is tartaric acid or a salt thereof, citric acid or a salt thereof, hydrochloric acid or a salt thereof, acetic acid or a salt thereof, maleic acid or a salt thereof, malic acid or a salt thereof, sulfuric acid or a salt thereof, toluenesulfonic acid or a salt thereof,

benzenesulfonic acid or a salt thereof, naphthalenesulfonic acid or a salt thereof, or ethanesulfonic acid or a salt thereof.

10. The formulation as defined in Claim 9 further including a base to
5 adjust pH of the aqueous formulation to within the range from about 3.5 to about 5.

11. The formulation as defined in Claim 8 wherein the substituted β -cyclodextrin is employed in a weight ratio to the aripiprazole within the range from about 10:1 to about 100:1.

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12. The formulation as defined in Claim 8 wherein the acid buffer is employed in a weight ratio to the aripiprazole within the range from about 2:1 to about 10:1.

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13. The formulation as defined in Claim 5 wherein the aripiprazole is present in an amount to provide a dosage from about 1 to 10 mg aripiprazole/mL.

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The formulation as defined in Claim 5 wherein the substituted β -cyclodextrin is SBEDC and is present in a weight ratio to aripiprazole within the range from about 20:1 to about 40:1.

15. The formulation as defined in Claim 5 wherein the aripiprazole and the substituted- β -cyclodextrin are in the form of an inclusion complex.

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The formulation as defined in Claim 5 wherein the formulation produces minimal irritation at the injection site.

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An aqueous injectable formulation comprising aripiprazole, SBEDC, tartaric acid, sodium hydroxide and water, said formulation having a pH within the range for about 4 to about 4.6.

18. The formulation as defined in Claim 17 comprising aripiprazole in an amount to provide from about 1.5 to about 8 mg/mL of formulation, SBECD in an amount with the range from about 100 to about 200 mg/mL; tartaric acid in an amount within the range from about 7 to about 9 mg/mL sodium hydroxide qs to adjust pH 5 within the range from about 4 to about 4.6; and water qs to 1 mL.
19. The formulation as defined in Claim 18 wherein the aripiprazole and the SBECD form an inclusion complex.
- 10 20. The formulation as defined in Claim 17 designed for intramuscular administration without causing unacceptable irritation.
- 15 21. The formulation as defined in Claim 15 wherein the inclusion complex provides an amount of aripiprazole of at least 2 mg aripiprazole/mL when the amount of aripiprazole provided by said complex, is measured at a substituted- β -cyclodextrin concentration of 5% w/v in water.
- 20 22. A method for administering injectable aripiprazole to a patient in need of treatment without causing unacceptable irritation at the site of injection, which comprises administering to a patient in need of treatment the formulation as defined in Claim 17.
- 25 23. The method as defined in Claim 22 wherein the formulation is administered intramuscularly.
24. A method of treating schizophrenia, which comprises administering to a patient in need of treatment the formulation as defined in Claim 5 without causing undue irritation at the site of administration.